

The CFAST Project and Comet Initiative COS

Rhonda Facile, MS
Vice President, Standards Development

Erin Muhlbradt, PhD.
National Cancer Institute – Enterprise Vocabulary Service



Strength through Collaboration

What is CDISC?

Clinical Data Interchange Standards Consortium

- Global Standards Development Organization (SDO)
- Founded in 1997 (all volunteers)
- Incorporated in 2000 as a non-profit organization
- Over 300 member organizations
- *Strength through Collaboration*
- 90 countries; Coordinating Committees in Europe, Japan, China, Asia-Pacific; 20 user networks
- Robust education program
- CDISC Standards
 - Streamline research processes and enable data sharing/aggregation
 - Support all types of research from protocol through analysis and reporting
 - Include link to healthcare through EHRs

The CDISC Vision: *informing patient care and safety through higher quality medical research.*

Mission: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

- CDISC has established **worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical research data and metadata** to improve data quality and streamline medical and biopharmaceutical product development and research processes
- **Consensus-based** development
- Standards are **freely available** at www.cdisc.org
- IP Policy ensures **open standards**



CDISC Strength Through Collaboration

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About Standards Partnerships Resources News Education Events Membership

2017 Europe Interchange

24 - 28 April 2017
London, England

More Information

Standards Updates

FOUNDATIONAL
BRIDG 4.1.1

Current Controlled Terminology Release

SENDIG: Developmental and Reproductive Toxicology Version 1.0 (Provisional)

SEND Implementation Guide v3.1

Study Data Tabulation Model (SDTM) v1.5

News and Media

CDISC Standards Key to Meeting FDA Regulations, Research Goals

CDISC and the Changing Landscape of Standards Implementation

CDISC and Cohen Veterans Bioscience Partner to Establish the First Therapeutic Area Standard for PTSD

more

Events and Training

INTERCHANGES

2017 Europe Interchange
April 24, 2017 to April 28, 2017

2017 Japan Interchange
June 13, 2017 to June 15, 2017

SYMPOSIA

CDISC Symposium
November 16, 2016

Opportunities

Standards bring order to complexity.

www.cdisc.org

CDISC

- CDISC is a community of Data Scientists
- Work to ensure that clinical data can be **found, understood and used** appropriately
- CDISC Standards specify how to structure the data to support efficient data sharing for regulated clinical trials
- CDISC Standards Do Not specify what data should be collected or how to conduct clinical trial protocols, assessments or endpoints
- CDISC works with Clinical Experts to help understand key concepts and translate them correctly into CDISC standards

Achieving Interoperability

BRIDG

HL7 RIM

HEALTHCARE

Healthcare Link

Patients



Healthcare Link

CLINICAL & NON-CLINICAL RESEARCH

Protocol

PRM
Study Design

ODM/
SDM
XML
→

Data Collection

CDASH
CDISC-Lab

ODM
XML
→

Tabulation
& Analyses

SEND
SDTM
ADaM

Dataset
XML
→
Define
XML

Submission/
Publication
Reporting

SEND
SDTM
ADaM

Controlled Terminology

THERAPEUTIC AREA STANDARDS & QUESTIONNAIRES

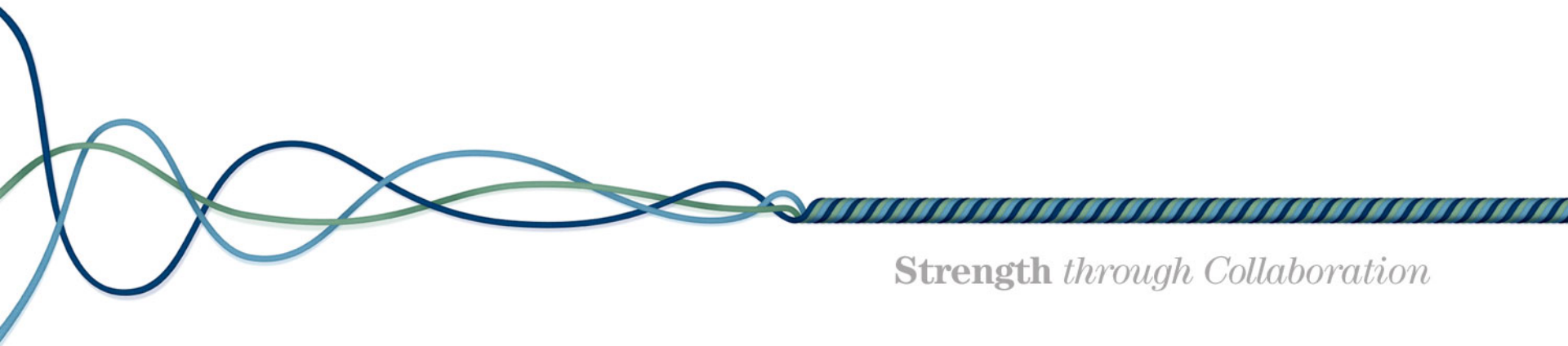
CDISC SHARE

Foundational Standards

Data Exchange

Semantics

Regulatory Drivers



Strength through Collaboration

Requirement of Study Data Standards – Data Exchange Standards



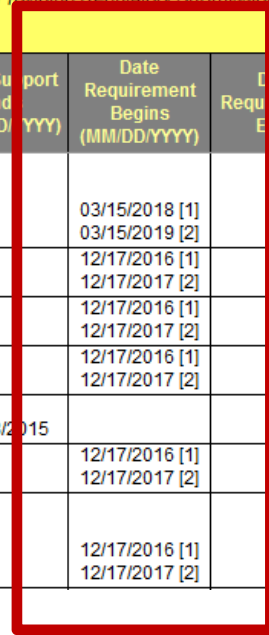
FDA Data Standards Catalogue v4.4

<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>

FDA Data Standards Catalog v4.4 (08-17-2015) - Supported and Required Standards

This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data* (<http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf>).

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Clinical study datasets	Study Data Tabulation Model (SDTM)	XPT	Interchange Standards Consortium (CDISC)	1.4	3.2	CDER, CBER	17/08/2015		03/15/2018 [1] 03/15/2019 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.3	3.1.3	CDER, CBER	12/01/2012		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	Version 3.1.2 Amendment 1	CDER, CBER	08/07/2013		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.2	3.1.2	CDER, CBER	30/10/2009		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SDTM
Clinical study datasets	SDTM	XPT	CDISC	1.1	3.1.1	CDER, CBER	Ongoing	01/28/2015			CDISC.org - SDTM
Clinical study datasets	Analysis Data Model (ADaM)	XPT	CDISC	2.1	1.0	CDER, CBER	Ongoing		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - ADaM
Animal study datasets	Standard for Exchange of Nonclinical Data (SEND)	XPT	CDISC	1.2	3.0	CDER	06/13/2011		12/17/2016 [1] 12/17/2017 [2]		CDISC.org - SEND

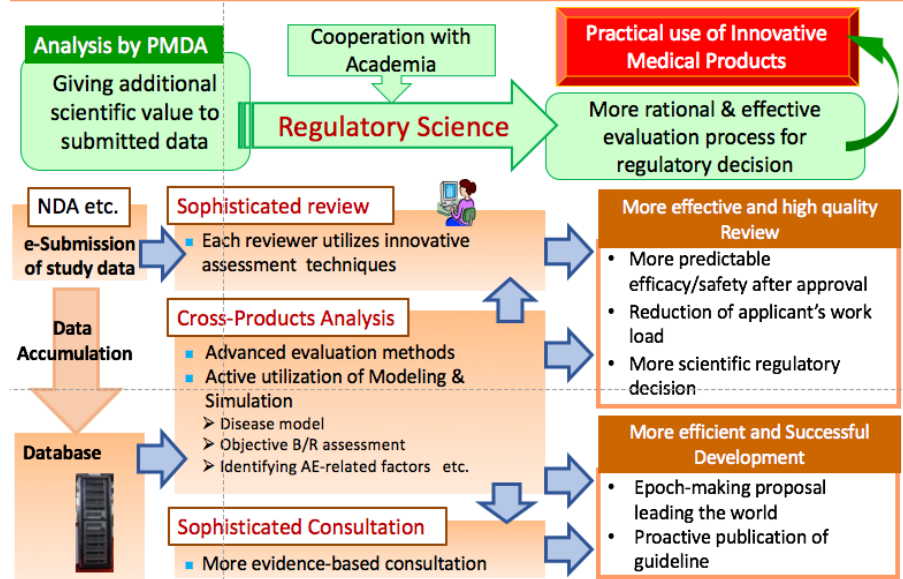


- Required e-Study Data for NDA's using CDISC **Oct 1st, 2016**

- CDISC TA Standards may be used in NDA applications

(Slides courtesy Hiroshi Sakaguchi, PMDA)

PMDA will require e-Study Data for NDA from **Oct 1st, 2016**



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Notifications and a Guide for study data submission

Basic Principles on Electronic Submission of Study Data for New Drug Applications

- Published on June 20, 2014, by Ministry of Health, Labour and Welfare

Notification on Practical Operations of Electronic Study Data Submissions

- Published on April 27, 2015, by Ministry of Health, Labour and Welfare
- Practical issues

Technical Conformance Guide on Electronic Study Data Submissions

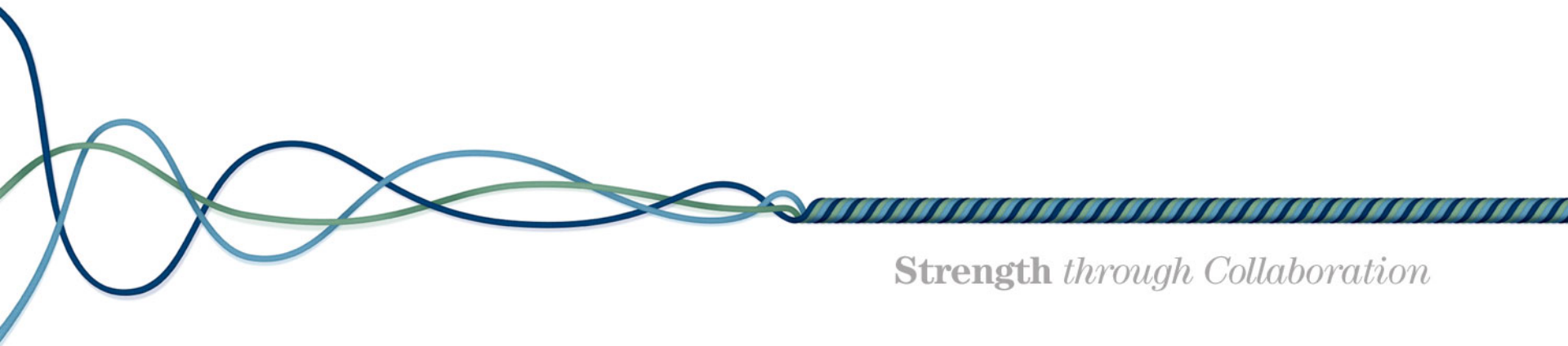
- Published on April 27, 2015, revised on June 30 and August 24, 2016 by PMDA
- Technical details

4.1.4 Therapeutic area standards

- To date, the **Therapeutic Area Standards** have been published for a number of diseases by the CDISC for storing data specific to each therapeutic area.
- These standards may be used for diseases for which standards have already been published.**
- However, the standards used must be provided in the definition document of the dataset and the data guide.

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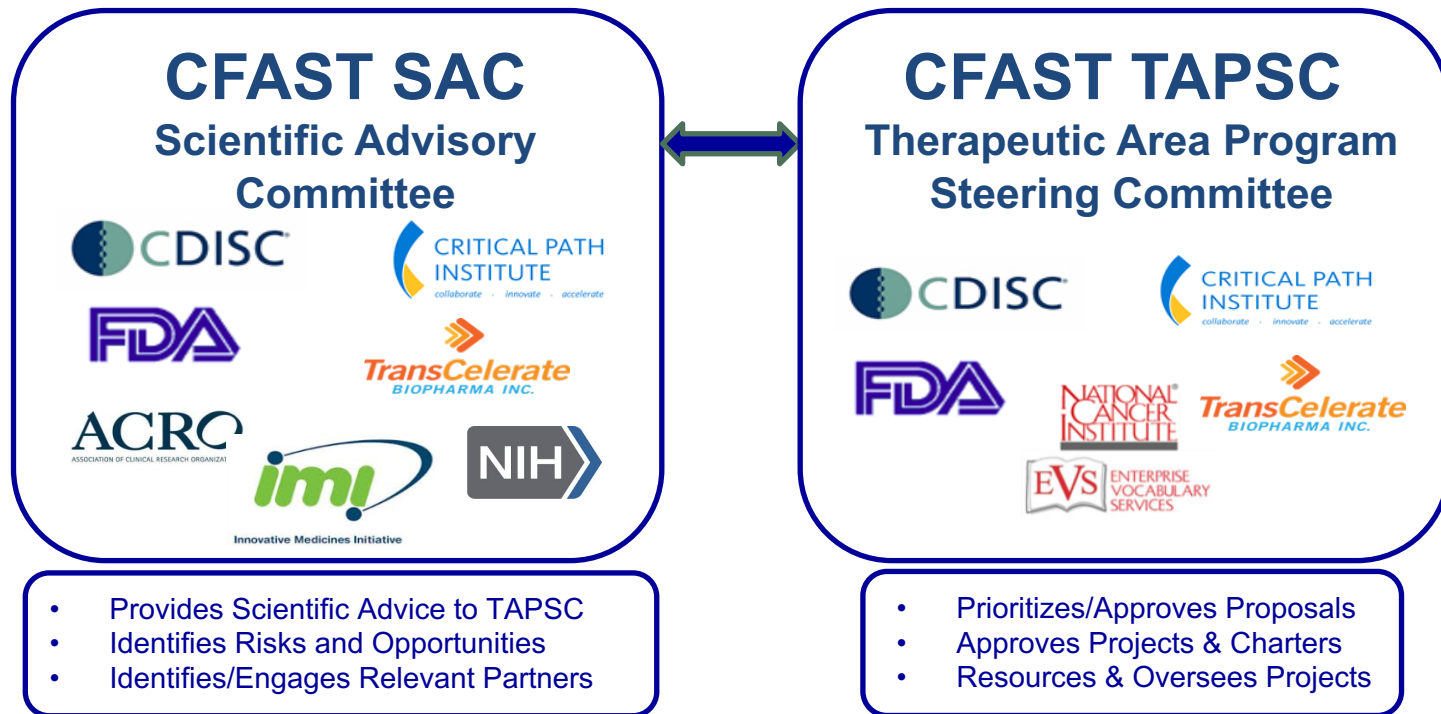
CFAST



Strength through Collaboration

Collaborations & Governance

*CFast is an **initiative** of CDISC and the Critical Path Institute to accelerate clinical research and medical product development by facilitating the creation and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health.*



Working Principles

- Focus on **core** concepts that apply to all phases of clinical trials in a specific TA
 - Aligns nicely with Comet's COS's ("represent the minimum that should be measured and reported in all clinical trials of a specific condition")
- Use CDISC SHARE tools, where possible
 - to develop concept metadata, annotated CRFs, etc.
- Start with the end in mind
 - then develop beginning to end TA standards (Protocol - CDASH - SDTM - ADaM) harmonized with existing CDISC Foundational Standards
- Reuse content, whenever possible, to assemble TA packages
 - Use previously developed content across TA standards as applicable (e.g., breast cancer - prostate cancer)

Example Concept Map

- Illustrates relationships among concepts and attributes
- Facilitates understanding (semantic interoperability) among functions involved in standards development

Self-Monitoring Blood Glucose (SMBG) – example

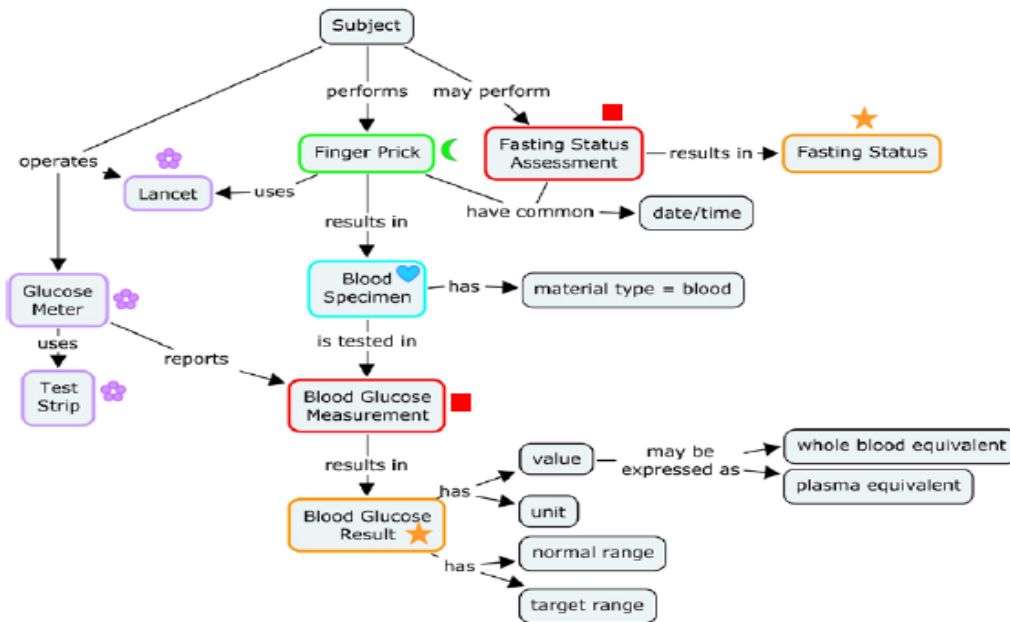


Diagram 2: Self-Monitoring Blood Glucose

Glucose measurements typically performed by subjects with diabetes are indicated. The glucose meter device requires a whole blood sample, but the glucose reading may be read as either a whole blood equivalent or a plasma equivalent.

What is in a TA Standard?

Advice

Examples

Explanations

Concept
Maps

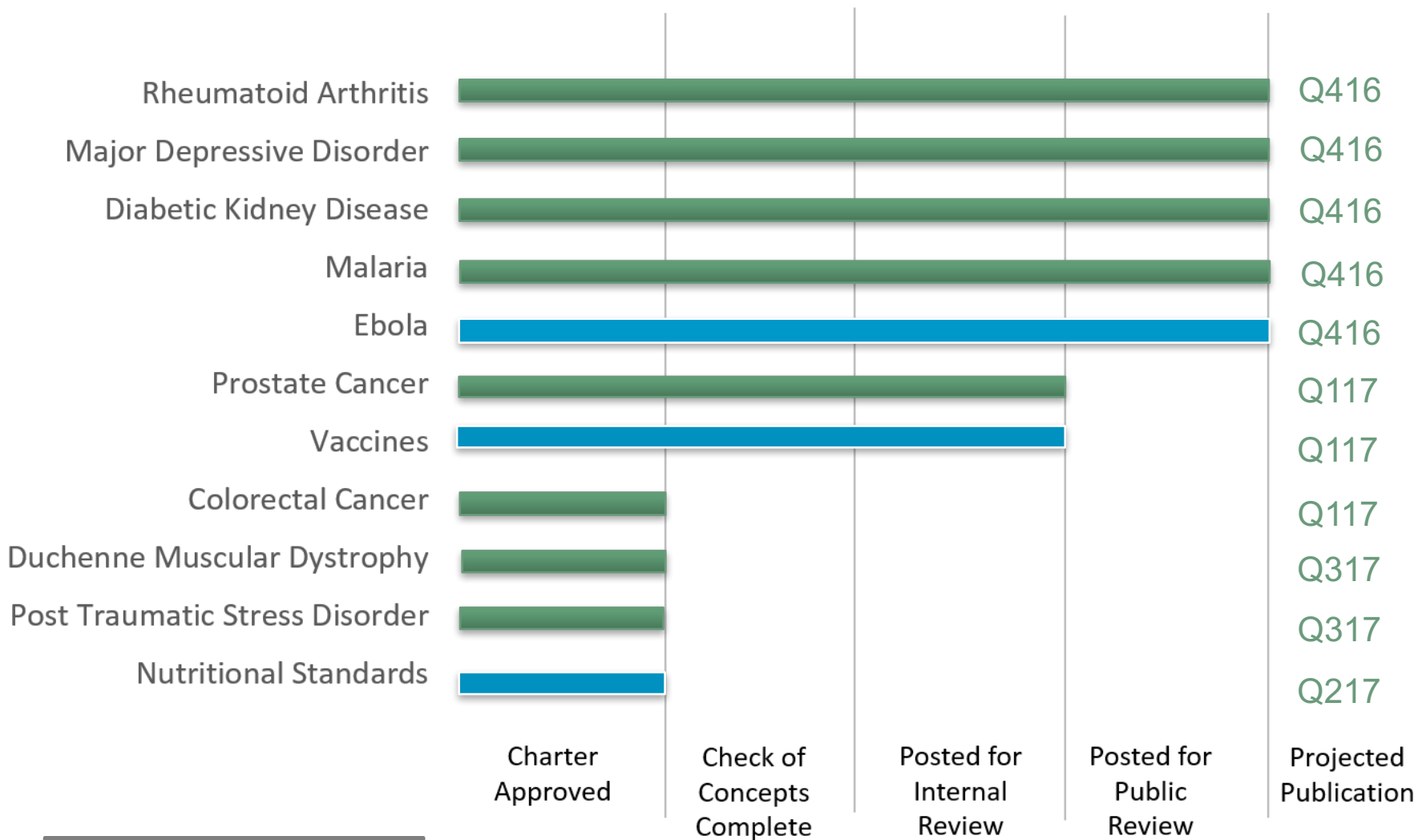
References

CFAST TA Standards Pipeline

Pre-CFAST	2012-2015	2015	2016	2017
Alzheimer's v1	Asthma v1	Traumatic Brain Injury v1 <i>One Mind</i>	Kidney Transplant <i>FDA-CFAST Yr3</i>	Oncology – Lung <i>FDA</i>
Pain <i>Univ of Rochester</i>	Alzheimer's v2 <i>C-Path CAMD Consortium</i>	Oncology - Breast	Oncology – Colorectal <i>FDA</i>	<i>CDAD FDA</i>
Parkinson's v1	Multiple Sclerosis <i>MS Society</i>	COPD	Malaria <i>Gates / WWARN</i>	Parkinson's v2 <i>C-Path CPP Consortium</i>
Polycystic Kidney Disease v1 <i>PKD Foundation</i>	Diabetes v1	Virology v2 <i>FDA</i>	Post Traumatic Stress <i>Cohen Veterans Bioscience</i>	Other tbd: Blood Cancer Osteoporosis, Hepatitis B
TB v1 <i>Gates</i>	Cardiology Endpoints v1 <i>FDA</i>	TB v2 (pediatrics) <i>C-Path CPTR Consortium</i>	Duchenne Muscular Dystrophy <i>FDA – CFAST Yr3/C-Path D-RSC Consortium</i>	Skin and Skin Structure Infections
Virology v1	Influenza <i>FDA</i>	Rheum. Arthritis	Ebola	
	Hepatitis-C <i>FDA</i>	Cardiology Imaging	General Anxiety Disorder /Biopolar	,
	Schizophrenia <i>FDA</i>	Oncology – Prostate <i>FDA</i>	<i>HIV - FDA</i>	
	Dyslipidemia	Major Depression <i>FDA CFAST Yr3</i>	<i>Huntington's CHDI</i>	

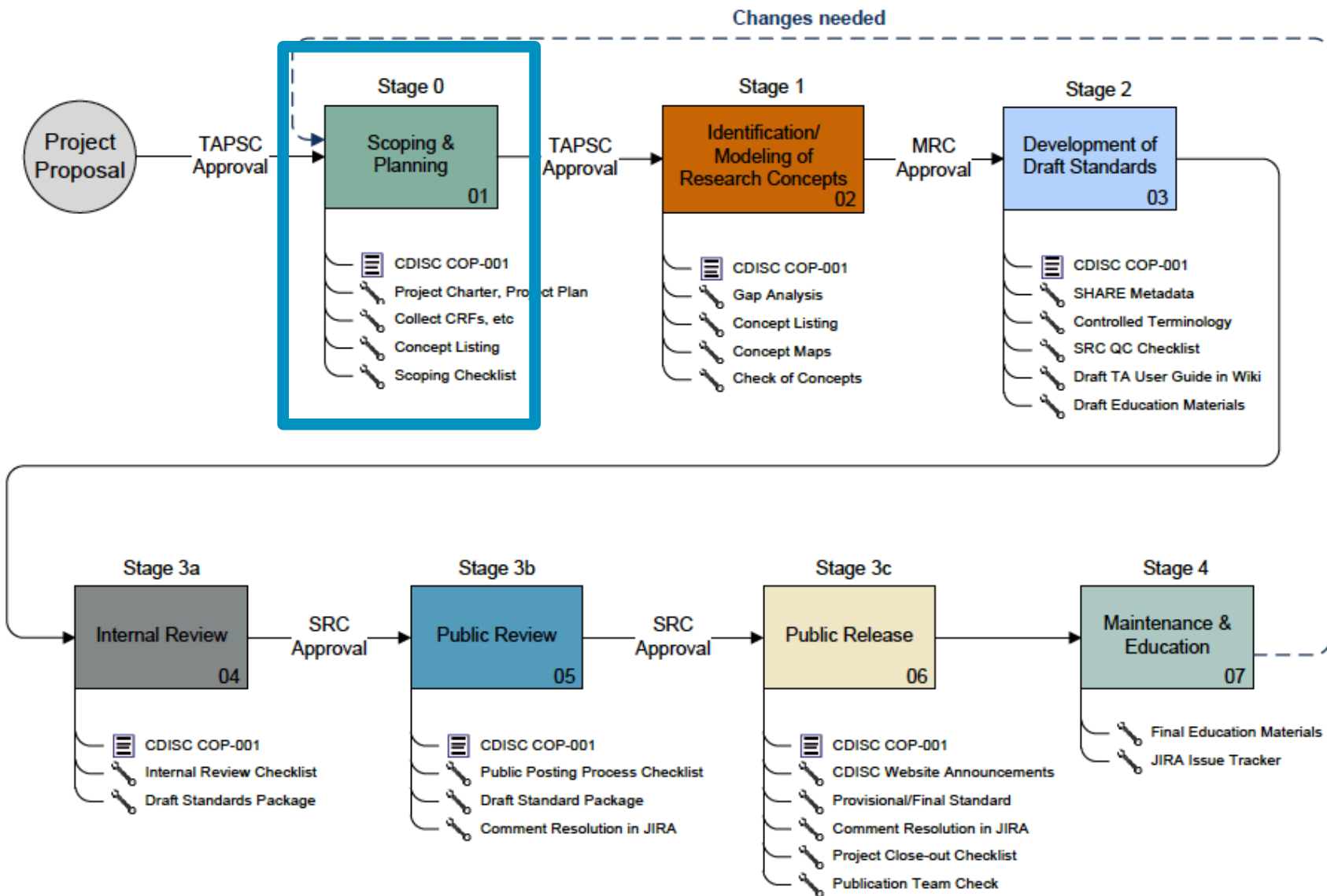
http://www.cdisc.org/system/files/all/CFAST_ProjectPipeline.pdf

Program Status



23 published TA standards to date

- █ Stakeholder resourced
- █ Volunteer resourced



TAPSC = Therapeutic Area Program Steering Committee
 MRC = Modeling Review Committee
 SRC = Standards Review Council

Where we Found Comet Useful

- COMET Database Searches yielded results for Prostate Cancer, Colorectal Cancer, infectious diseases scoping
- We reference papers from the COMET database for bibliographical purposes within TA projects
 - The papers help us to understand the clinical background
 - COMET has good holdings in the oncology and infectious diseases areas
 - TA teams especially benefit from papers that contain lists of questionnaires

Prostate Cancer

Full Name and Abbreviation	Permission	Status of Supplement
The Expanded Prostate Cancer Index Composite Short Form (EPIC-26)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)
Expanded Prostate Cancer Index Composite for Clinical Practice (EPIC-CP)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)
EORTC QLQ-PR25	Denied	Controlled Terminology for QSTESTCD and QSTEST, Implementation Guide, will not be developed; Controlled Terminology for QSCAT in development
EORTC QLQ-C30	Denied	Controlled Terminology for QSTESTCD and QSTEST, Implementation Guide, will not be developed; Controlled Terminology for QSCAT in development
EORTC QLQ-C15-PAL	Denied	Controlled Terminology for QSTESTCD and QSTEST, Implementation Guide, will not be developed; Controlled Terminology for QSCAT in development
Functional Assessment of Cancer Therapy - General (Version 4) (FACT-G)	Granted	Controlled Terminology developed; Implementation Guide in development
Functional Assessment of Cancer Therapy - Prostate (Version 4) (FACT-P)	Granted	Controlled Terminology developed; Implementation Guide in development
FACT/NCCN-Prostate Symptom Index (Version 2) (FACT/NCCN FPSI-17)	Granted	Controlled Terminology developed; Implementation Guide in development
European Quality of Life Questionnaire (EQ-5D-3L)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)
European Quality of Life Questionnaire (EQ-5D-5L)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)
Prostate Cancer Specific Quality of Life Instrument	Granted	Controlled Terminology developed; Implementation Guide in development
Brief Fatigue Inventory (BFI)	Pending	In development
Brief Pain Inventory - Short Form (BPI-SF)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)
Brief Pain Inventory (BPI)	Granted	Implementation Guide available on CDISC website (www.cdisc.org/qrs)

(Chen RC et al, Recommended patient-reported core set of symptoms to measure in prostate cancer treatment trials, J Natl Cancer Inst (2014) 106(7))

Where we Found Comet Useful

- Review of Comet COS helps to speed the scoping process by helping point to key clinical concepts and building knowledge for therapeutic areas
 - Listings of relevant Questionnaires, ratings and scales are very helpful
- The CFAST program will continue to review and reference Comet Initiative holdings on CFAST TA standards development projects.

Acknowledgements

National Cancer Institute –
Enterprise Vocabulary Service

